RES-096: Oteseconazole Versus Fluconazole for the Treatment of Severe Vulvovaginal Candidiasis: A Post Hoc Analysis by *Candida Species*

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APCCMI2025 BANGKOK

Background

- Oteseconazole, a novel selective fungal CYP51 inhibitor, has demonstrated to be superior to fluconazole for the treatment of severe vulvovaginal candidiasis (SVVC).
- This post-hoc study was aimed to explore the efficacy and safety of oteseconazole in SVVC caused by different *Candida species*.

Methods

- This post hoc analysis was based on a randomized, double-blinded, phase 3 trial (NCT04956419; Figure 1).
- Female participants with a vulvovaginal signs and symptoms score of ≥7 and positive Candida species were randomly assigned (1:1) to receive oteseconazole (600 mg on D1 and 450 mg on D2) or fluconazole (150 mg on D1 and D4).
- The trial was conducted between April 2021 and October 2021 at 26 sites in China.
- Main study outcomes were therapeutic cure (the achievement of both clinical and mycological cure), clinical cure (absence of both VVC signs and symptoms), and mycological cure (culture-negative of vaginal swabs for Candida species) at day 28.

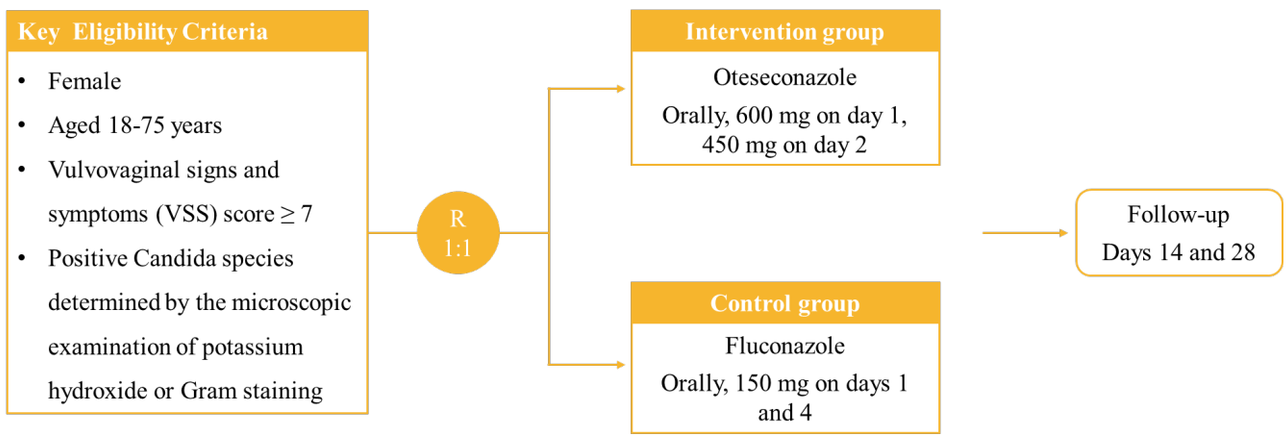

Figure 1. Study Design

Results

Baseline characteristics

- Overall, 319 participants had a confirmed *Candida*-positive culture (249 positive for *Candida albicans* and 70 for non-*Candida albicans*).
- The detailed baseline characteristics are listed in Table 1.

Table 1. Baseline characteristics

	Candida albicans subgroup		Non-*Candida albicans* subgroup	
	Oteseconazole (*n* = 128)	Fluconazole (*n* = 121)	Oteseconazole (*n* = 32)	Fluconazole (*n* = 38)
Age (year), mean (SD)	29.6 (8.22)	30.8 (7.32)	31.3 (6.77)	32.3 (7.95)
Ethnicity, *n* (%)				
Han	123 (96.1)	114 (94.2)	29 (90.6)	35 (92.1)
Other	5 (3.9)	7 (5.8)	3 (9.4)	3 (7.9)
Weight (kg), mean (SD)	56.0 (9.05)	55.6 (9.04)	58.8 (9.81)	55.6 (7.78)
BMI (kg/m^2), mean (SD)	21.1 (3.51)	21.4 (3.15)	22.3 (3.33)	21.9 (3.16)
Composite VSS score, mean (SD)	8.8 (1.81)	8.6 (1.93)	8.0 (1.31)	7.8 (1.28)
Susceptibility testing, *n* (%)*				
Oteseconazole				
Sensitive	126 (98.4)	119 (98.3)	29 (90.6)	35 (89.7)
Resistant	2 (1.6)	2 (1.7)	1 (3.1)	1 (2.6)
Dose-dependently sensitive	0	0	0	0
Wild strain	0	0	1 (3.1)	1 (2.6)
Unknown	0	0	1 (3.1)	2 (5.1)
Fluconazole				
Sensitive	90 (70.3)	89 (73.6)	26 (81.3)	28 (71.8)
Resistant	12 (9.4)	12 (9.9)	3 (9.4)	5 (12.8)
Dose-dependently sensitive	26 (20.3)	20 (16.5)	2 (6.3)	5 (12.8)
Wild strain	0	0	1 (3.1)	1 (2.6)
Unknown	0	0	0	0

*One patient with fluconazole in Non-*Candida albicans* subgroup presented with two strains (Candida parapsilosis and Kodamaea ohmeri). BMI, body mass index; SD, standard deviation; VSS, vulvovaginal signs and symptoms.

Results (continued)

Efficacy

- In the *Candida albicans* subgroup, oteseconazole was associated with greater odds of achieving therapeutic cure, clinical cure, and mycological cure at day 28. In the non-*Candida albicans* subgroup, only the odds of achieving therapeutic cure and mycological cure were greater with oteseconazole (Figure 2). No interaction was observed by *Candida* species (all $P_{interaction} > 0.05$).

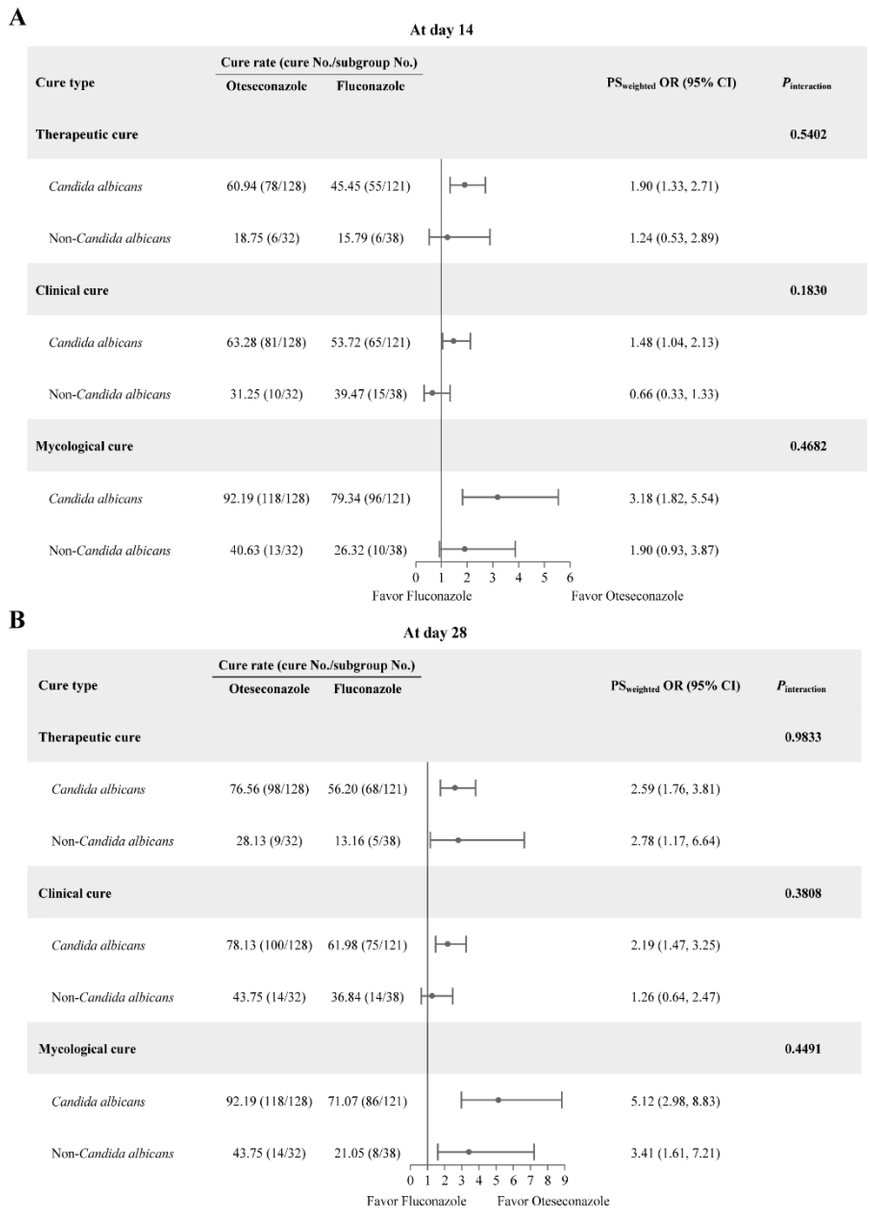

Figure 2. Therapeutic cure, clinical cure, and mycological cure with oteseconazole versus fluconazole at day 14 (**A**) and day 28 (**B**). PS, propensity scores; OR, odds ratio; CI, confidence interval.

Safety

- Adverse events were generally similar between treatment groups, regardless of *Candida* species (Table 2).

Table 2. Summary of TEAEs

	Candida albicans subgroup		Non-*Candida albicans* subgroup	
	Oteseconazole (*n* = 127)	Fluconazole (*n* = 121)	Oteseconazole (*n* = 32)	Fluconazole (*n* = 38)
Any TEAEs, *n* (%)	62 (48.8)	53 (43.8)	20 (62.5)	16 (42.1)
Any serious TEAEs, *n* (%)	0	1 (0.8)	0	0
TEAE leading to death, *n* (%)	0	0	0	0
TEAEs leading to treatment discontinuation, *n* (%)	0	0	0	0
The most common TEAEs*, *n* (%)				
Urinary tract infection	9 (7.1)	5 (4.1)	4 (12.5)	2 (5.3)
Bacterial vulvovaginitis	6 (4.7)	11 (9.1)	1 (3.1)	1 (2.6)
Bacterial vaginosis	1 (0.8)	7 (5.8)	1 (3.1)	3 (7.9)
Nausea	5 (3.9)	5 (4.1)	0	0
Upper respiratory tract infection	3 (2.4)	2 (1.7)	2 (6.3)	2 (5.3)
Dizziness	6 (4.7)	3 (2.5)	0	0
Abdominal discomfort	1 (0.8)	0	3 (9.4)	1 (2.6)
Diarrhoea	1 (0.8)	2 (1.7)	2 (6.3)	0
White blood cell count decreased	1 (0.8)	0	0	2 (5.3)

*TEAEs occurring in >4% of patients in any subgroup. TEAE, treatment-emergent adverse events.

Conclusions

- Oteseconazole shows potential benefit over fluconazole in treating SVVC caused by *Candida albicans* and non-*Candida albicans* species, with a manageable safety profile.